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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1 53(b))

Attorney Docket	661005.90268
First Inventor	Michael C. Barney
Title	ANTIMICROBIAL DIAPERS AND WET WIPES
Express Mail Label No.	EJ636885455US

APPLICATION ELEMENTS

See MPEP Chapter 600 concerning utility patent application contents

ADDRESS TO: **Commissioner for Patents, Box Patent Application, Washington, D.C. 20231**

1. [X] Fee transmittal Form (Submit an original and a duplicate for fee processing)
2. [ ] Applicant claims small entity status See 37 CFR 1.27.
3. [X] Specification [Total Pages 14] *(preferred arrangement set forth below)*
   - Descriptive title of the invention
   - Cross References to Related Applications
   - Statement Regarding Fed Sponsored R&D
   - Reference to sequence listing, a table or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. [ ] Drawing(s) (35 USC 113) [Total Sheets]
5. Oath or Declaration [Total Pages 3]
   - a [X] Newly executed (original or copy)
   - b [ ] Copy from prior Application (37 CFR 1.63(d)) (for continuation/divisional with Box 17 completed)
     - [ ] DELETION OF INVENTOR(S) named in prior application, see 37CFR 1.63(d)(2) and 1.33(b).
   - [ ] Application Data Sheet. Se 37 CFR 1.76
7. [ ] CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
   - a. [ ] Computer Readable Form (CRF)
   - b. *Specification Sequence Listing on*
     - [ ] CD-ROM or CD-R (2 Copies); or
     - [ ] paper
   - c. [ ] Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. [X] Assignment Papers (cover sheet & documents)
10. [ ] 37 CFR 3.73(b) Statement (where there is an assignee) [X] Power of Attorney
11. [ ] English Translation Document *(if applicable)*
1. [X] Information Disclosure Statement (IDS)/PTO-1449 [X] Copies of IDS Citations
1. [ ] Preliminary Amendment
1. [X] Return receipt postcard (MPEP 503) *(Should be specifically itemized)*
15. [ ] Certified copy of priority Document(s) *(if foreign priority is claimed)*
1. [ ] Other:

17. **If a CONTINUING APPLICATION,** check appropriate box and supply the requisite information: and in a preliminary amendment or in an Application Data Sheet under 37 CFR 1.76

[ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application no. ___/_____

Prior application information: Examiner: Group/Art Unit:

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

18. CORRESPONDENCE ADDRESS

[ ] Customer Number or Bar Code Label (Insert Customer No. or Attach bar code label here) or [X] Correspondence address below

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Signature	David G. Ryser	Date: October 20, 2000	

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FEE TRANSMITTAL for FY 2001

Patent fees are subject to annual revision.
Small Entity payments must be supported by a small entity statement
otherwise large entity fees must be paid, See Forms PTO/SB/09-12
See 37 C.F.R. §§1.27 and 1.28

TOTAL AMOUNT OF PAYMENT	$710.00

Complete if Known	
Application Number	
Filing Date	October 20, 2000
First Named Inventor	Michael C. Barney
Group Art Unit	
Examiner Name	
Attorney Docket Number	661005.90268

fc813 U.S. Pro 09/693123 10/20/00

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 17-0055

Deposit Account Name: Quarles & Brady LLP

[X] Charge Any Additional Fee Required Under 37 CFR 1 16 and 1 17

2. [ ] Payment Enclosed:

[ ] Check [ ] Money Order [ ] Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	710	201	355	Utility filing fee	$710.00
106	320	206	160	Design filing fee	
107	490	207	245	Plant filing fee	
108	710	208	355	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($)710.00

2. CLAIMS

		Extra		Fee from below		Fee Paid
Total Claims	7	-20**=	0	X 0	=	0
Independent	3	-3**=	0	X 0	=	0
Multiple Dependent Claims				0	=	0

** or number previously paid, if greater, For reissues see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	80	202	40	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim
109	80	209	40	Reissue independent claims over original patent
110	18	210	9	Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920	112	920	Requesting publication of SIR prior to Examiner action	
113	1,840	113	1,840	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	390	216	195	Extension for reply within second month	
117	890	217	445	Extension for reply within third month	
118	1,390	218	695	Extension for reply within fourth month	
128	1,890	228	945	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive unavoidably abandoned application	
141	1,240	241	620	Petition to revive unintentionally abandoned application	
142	1,240	242	620	Utility issue fee (or reissue)	
143	440	243	220	Design issue fee	
144	600	244	300	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	710	246	355	Filing a submission after final rejection (37 CFR 1.129(a))	
149	710	249	355	For each additional invention to be examined (37 CFR 1.129(b))	
179	710	270	355	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	
Other fee (specify)					

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($)

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	David G. Ryser	Registration No. (Attorney/Agent)	36,407	Telephone	414-277-5717
Signature	David G. Ryser			Date	October 20, 2000

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ANTIMICROBIAL DIAPERS AND WET WIPES

CROSS REFERENCES TO RELATED APPLICATIONS

Not applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not applicable.

BACKGROUND OF THE INVENTION

This invention relates to the application of specific antimicrobial agents to diapers and wet wipes for the protection of infants from strains of the bacterium *Staphylococcus aureus,* which is known to be a causative agent of toxic shock syndrome (TSS). Toxic shock syndrome is a severe, toxin-induced disease caused by infection with toxic shock syndrome toxin-1 (TSST-1) (Iandolo, Ann. Rev. of Micro. 43:275-402, 1989) which is produced by *Staphylococcus aureus,* and is characterized by sudden onset of symptoms including high fever, chills, rash, vomiting and/or diarrhea, and a rapid drop in blood pressure, which often leads to shock. While most commonly seen in menstruating women, in whom the primary site of infection is vaginal, the syndrome has also been reported in infants, children, men, and nonmenstruating women at a lower frequency rate. In such cases, skin wounds or *Staphylococcus aureus* infection in other sites in the body are believed to be the cause of TSS. The rate of incidence of the syndrome in the United States is about two cases per 10,000 persons annually.

While the disease may be treated with antibiotics and by administration of intravenous fluids to maintain blood pressure, many persons suffering from toxic shock syndrome may not receive appropriate medical intervention before serious complications result, due to the sudden onset of the syndrome. This is particularly true in the case of infants and children. Typically, such

complications may include kidney failure, heart failure, liver failure, and profound shock.

Because TSS has such a rapid onset, and may be life-threatening, there is a very strong emphasis on disease prevention, with most of the concentration being upon menstruating women, who are at increased risk of developing TSS through the use of highly absorbent tampons or barrier contraceptives. Various approaches to preventing the development of toxic shock syndrome from tampon use have been advanced, including incorporating bactericidal or bacteriostatic agents such as antibiotics or phenol into tampons to inhibit grown of *Staphylococcus aureus*; incorporating agents which prevent the production of TSST-1, or inactivate TSST-1; and mechanical improvements to tampons which prevent harmful bacteria from being introduced into or colonizing within the vagina.

A number of U.S. Patents have issued relative to this matter, including U.S. 4,405,323, the content of which is incorporated herein by reference, as if fully set forth herein, which discloses a tampon having an antibacterial agent such as povione-iodine, mercury, zinc, penicillin, erythromycin, or nitrofurazone, incorporated therein. U.S. Patent 4,431,427, the content of which is incorporated herein by reference, as if fully set forth herein, discloses a tampon incorporating a water-soluble acid, such as citric, glycolic, malic, tartaric, or lactic acid, in an amount sufficient to maintain a pH of less than 4.5 in the fluids absorbed in a tampon, so as to inhibit growth of pathogenic bacteria.

It is also known that some hop acids produced in the brewing of beer can inhibit the growth of microorganisms. U.S. Patent 5,082,975, the content of which is incorporated herein by reference, as if fully set forth herein, discloses that the hop acid hexahydrolupulone can inhibit the growth of *Lactobacillus* without inhibiting yeast. Similarly, U.S. Patent 5,455,038, the content of which is incorporated herein by reference, as if fully set forth herein, teaches that Listeria in a medium or in food may be inhibited by contact with an effective amount of hexahydrocolupulone, tetrahydroiso-

humulone, or a salt of hexahydrocolupulone or tetrahydroisohumulone. Hop acids are relatively inexpensive, making their use to inhibit growth of organisms attractive. Also, resistance of *Staphylococcus aureus* has not been described as has the resistance to various antibiotics. The term "tetrahydroisohumulone" as used herein includes a mixture of tetrahydroisohumulone, tetrahydroisoadhumulone and tetrahydroisocohumulone. The mixture is commercially available, or can be prepared for example by use of the method of the Cowles *et al.* U.S. Patent 4,644,084, the content of which is incorporated herein by reference, as if fully set forth herein. The hexahydrocolupulone is a known compound which can be made by the chemical hydrogenation of colupulone with platinum (IV) oxide as the catalyst as described by W. Reidl, J. Nickl, *Ber*; 89 (1956) p. 1863, or J. F. Carson, J. Am. Chem. Soc., 73 (1951) p. 1850.

Further, Nutter *et al.* disclosed in U.S. Patent 5,827,895, the content of which is incorporated herein by reference, as if fully set forth herein, that hexahydrolupulones and hexahydrocolupulones may be used to inhibit the growth of *Staphylococcus aureus.* Nutter *et al.* also reported that the antimicrobial activity of hexahydrolupulones is highly specific for gram positive bacteria, such as *Staphylococcus aureus.*

In addition, Todd et al, in U.S. Patent 5,166,449, the content of which is incorporated herein by reference, as if fully set forth herein, note the antibacterial activity of beta acids (lupulone), as a constituent of hops, and methods for their conversion to tetrahydroiso-alpha and hexahydro-beta acids. The patent also teaches the use of such compounds for inhibition of the bacterium Lactobacillus.

However, no methods have to date been found to effectively eliminate or inhibit growth of *Staphylococcus aureus,* or toxins produced thereby, in skin wounds or other sites of the body, particularly in infants. Since infants are sensitive to TSS, and infants of diaper wearing age particularly so, a means to prevent TSS associated with infection from skin contact has been sought.

BRIEF SUMMARY OF THE INVENTION

The present invention provides a means for prevention of TSS in infants of diaper wearing age, by provision of diapers and wet wipes for use in cleansing of infants, wherein said diapers and wet wipes contain an anti-microbial compound effective against TSST-1, and thus against TSS. It has now been discovered that certain hop acid derivatives are highly bactericidal to gram positive bacteria, and are particularly effective at killing *Staphylococcus aureus*, the causative agent of toxic shock syndrome, at extremely low concentrations. These derivatives are tetrahydroiso-alpha acids, and/or hexahydro-beta acids, and mixtures thereof. Both of these derivatives have now been found to have greatly enhanced antimicrobial properties compared to the hop acids, humulone and lupulone. The two derivatives may be used independently, or together, with positive effect.

When applied to diapers, particularly disposable diapers, these derivatives essentially eliminate the growth of *Staphylococcus aureus* and toxins associated therewith, including toxic shock syndrome toxin-1,in diapers in contact with the skin. These compositions may also be applied to wet wipes used to clean the infant when changing diapers, and will inhibit *Staphylococcus aureus* on skin surfaces, thus reducing the risk of toxic shock syndrome in infants of diaper wearing age.

It is thus an advantage of the present invention to provide an inexpensive method for inhibiting the occurrence of TSS in infants. It is a further advantage of the present invention to provide a wet wipe suitable for use not only on infants of diaper wearing age, but for use on any skin wound or area of possible infection, which is antimicrobial against Gram-positive bacteria, and particularly against *Staphylococcus aureus*. A still further advantage is that the effective medium is a naturally occurring derivative of a natural source, and is readily biodegradable as well as being safe for human consumption, in concentrations which will kill *Staphylococcus aureus* as well as other Gram-positive bacteria.

DETAILED DESCRIPTION OF THE INVENTION

Toxic shock syndrome is a serious, potentially fatal illness that occurs with sudden onset, and occurs primarily in menstruating women. However, toxic shock syndrome is also known to effect infants, children, men, and non-menstruating women, primarily from skin wounds or infection of other sites in the body by *Staphylococcus aureus* and the toxic shock syndrome toxin-1. It has now been found that certain specific hop-acid derivatives, specifically tetrahydroisoalpha acids and hexahydro-beta acids, will inhibit the growth of *Staphylococcus aureus* and other Gram-positive bacteria when applied topically to a skin wound, or when incorporated in a diaper or other dressing, such as a bandage, in contact with the skin.

Since toxic shock syndrome in infants has been attributed to the growth of *Staphylococcus* on baby diapers, the addition of anti-*Staphylococcus* compounds, specifically tetrahydroiso-alpha acids and hexahydro-beta acids, to materials used in disposable baby diapers as well as to wet wipes used to clean the baby during diaper changes would inhibit *Staphylococcus aureus* and reduce the risk of toxic shock syndrome. Tetrahydroiso-alpha acids and hexahydro-beta acids also inhibit all other Gram-positive bacteria tested, and to a lesser amount some Gram-negative bacteria, which may also colonize and grow in disposable baby diapers. Therefore, there would be an added benefit of helping to eliminate bacteria other than *Staphylococcus* that could cause potential infections.

The preferred embodiment of the present invention thus comprises incorporating a safe and effective concentration of tetrahydroiso-alpha acid, hexahydro-beta acid, or mixtures thereof, in the surface layer of a disposable diaper, or in the wetting solution of a wet wipe, to combat the growth of bacteria on infants. By the term "an effective amount of the compound" it is meant that sufficient of the compound is present to provide the desired anti-microbial effect, but not so much as to cause any undesirable result, or to be prohibitively expensive. By the term antimicrobial, it is meant that the compo-

sition, at a minimum, inhibits the growth of bacteria, and preferably, destroys such bacteria as are present.

It is known in the brewing industry that some hop acids can inhibit the growth of microorganisms that can cause spoilage in beer. Hop acids are relatively inexpensive, making their use in food products to inhibit growth of organisms attractive. From this recognition came the discovery that tetrahydroiso-alpha acids and hexahydro-beta acids have bactericidal or bacteriostatic activities against *Staphylococcus aureus*. This makes it possible to selectively inhibit *Staphylococcus aureus* in a culture by contacting the culture with a tetrahydroiso-alpha acid or hexahydro-beta acid in a concentration effective to inhibit *Staphylococcus aureus*.

To selectively inhibit *Staphylococcus aureus* in culture by contacting the culture with a tetrahydroiso-alpha acid or hexahydro-beta acid, the concentration of tetrahydroiso-alpha acid or hexahydro-beta acid is preferably is in the range of from about 0.1 ppm to about 100 ppm, based upon the total culture. More preferably, the concentration of tetrahydroiso-alpha acid or hexahydro-beta acid is about is in the range of from about 0.2 ppm to about 50 ppm of the total culture. Since the hop compounds utilized are relatively stable compounds, they may be used as a solution sprayed on the finished diapers, or applied as a liquid during manufacture of the diapers, and subsequently dried. Once the compounds are dried, with sufficient compound remaining in situ to provide an effective amount of the compound on the diaper in use, they are relatively stable.

The preferred mode of contacting the culture comprising *Staphylococcus aureus* with the hop acids is to place an absorbent material containing an effective amount of the hop acids in contact with or in proximity to the culture.

The following non-limiting examples are intended to be purely illustrative.

Examples

Minimal inhibitory concentration (MIC) assays of several hop compounds were conducted using a *Staphylococcus aureus* species as the test microorganism. The MCI assays for *Staphylococcus aureus* were conducted in Difco trypticase soy broth (TSB) tubes. A 0.1 ml aliquot of a 1% (w/w) solution of each hop acid in alcohol was added to a tube of sterile TSB broth to give a final concentration of 100 ppm of the hop. This solution was serially diluted in tubes with sterile broth using a two-fold dilution series. A second dilution series prepared as above, but using 0.1 ml alcohol without hop acid, was used as a positive control of bacterial growth. Each tube was inoculated with a fresh culture (10^4 cells) of a *Staphylococcus aureus* species in TSB broth. The pH of the TSB was adjusted to pH 7.0, pH 6.0, or pH 5.0 using hydrochloric acid. The tubes were incubated aerobically at 37°C for three days and growth was evaluated by visually assessing and scoring the development of turbidity in the broth.

The results of MIC assay of tetrahydroiso-alpha acids and hexahydro-beta acids on *Staphylococcus aureus* and are shown in Table 1.

As can be seen from Table 1, *Staphylococcus aureus* is very sensitive to both tetrahydroiso-alpha acids and hexahydro-beta acids. *Staphylococcus aureus* showed no growth or possibly very weak growth at tetrahydroiso-alpha acid or hexahydro-beta acid concentrations as low as 1.56 ppm at a neutral pH. Sensitivity of *Staphylococcus aureus* appears to increase under acidic conditions, with the minimum inhibitory concentration decreasing to 0.78 ppm at pH 6.0 and to 0.2 ppm at pH 5.0.

Table 1

MIC Assays of Tetrahydroiso-alpha Acids and Hexahydro-beta Acids using Staphylococcus aureus						
	TSB at pH 7.0		TSB at pH 6.0		TSB at pH 5.0	
Concentration (ppm)	Tetra	Hexa	Tetra	Hexa	Tetra	Hexa
100	No growth	No growth	No growth	No growth	No growth	No growth
50	No growth	No growth	No growth	No growth	No growth	No growth
25	No growth	No growth	No growth	No growth	No growth	No growth
12.5	No growth	No growth	No growth	No growth	No growth	No growth
6.25	No growth	No growth	No growth	No growth	No growth	No growth
3.125	No growth	No growth	No growth	No growth	No growth	No growth
1.56	+/- Growth	+/- Growth	No growth	No growth	No growth	No growth
0.78	+ Growth	+ Growth	No growth	No growth	No growth	No growth
0.39	++ Growth	++ Growth	+/- Growth	No growth	No growth	No growth
0.2	+++ Growth	+++ Growth	++ Growth	+ Growth	No growth	No growth
0	+++ Growth	+++ Growth	+++ Growth	+++ Growth	+++ Growth	+++ Growth

From this experimentation, it may be clearly seen that both tetrahydroiso-alpha acids and hexahydro-beta acids have strong antimicrobial or antibacterial properties, and are candidates for use in any application where they might be useful to combat *Staphylococcus aureus*, the primary causative agent in toxic shock syndrome.

For the purpose of applying these agents to combat toxic shock syndrome in infants, it was determined that directly incorporating them into the fabric of the diaper, or into the liquid present in a wet wipe to be used for cleansing of the infant, offered the greatest advantages. Various methods are known in the art for the application of liquid compositions to absorbent fabrics, and such methods are not considered as part of the present invention. Similarly, the addition of various components to the cleansing

agents used in wet wipes is well known in the art, and not considered part of the present invention. Rather, the present invention is related to the selection of the specific antimicrobial compositions used, i.e. the tetrahydroiso-alpha acids and hexahydro-beta acids, provided that sufficient of the composition is provided so as to be an effective antimicrobial composition when in contact with a site subject to microbial growth. The specified compositions are readily available as by-products of the brewing industry, at relatively low cost. Being products of naturally occurring compositions, these acids are biodegradable, and safe for human usage, particularly as envisioned.

For application to a disposable diaper, it is proposed that a suitable mixture incorporating an effective concentration of the tetrahydroiso-alpha acid, hexahydro-beta acid, or a mixture thereof, be applied to a woven or non-woven cellulose-containing substrate, such as a moisture absorbent fabric of the type commonly used for diapers. Such fabrics are well known in the art, and any suitable such material may be used, including those containing super absorbent materials. It is also possible, although less advantageous, to include the antimicrobial composition of the invention in conventional cotton or other fabric diapers suitable for washing and re-use, although the antimicrobial composition will be removed from the fabric during normal washing.

The tetrahydroiso-alpha and hexahydro-beta acids employed are known to be soluble in water. Alternatively, they are also soluble in such materials as ethanol (and other alcohols), propylene glycol, glycerine, and polyols, or mixtures thereof with or without water. Such materials are quite suitable for, and are frequently employed in, diapers and wet wipes. Since the compounds are poorly soluble in plain water, alcohols are frequently used to prepare a solution. When water is used, it may be adjusted to a mildly alkaline pH to increase the solubility of the compounds.

The hop acid antimicrobials may be incorporated into the absorbent fabric, such as a disposable diaper, in conventional fashion, such as by passage of the fabric from a supply roll, into a pad bath containing an

appropriate concentration of the antimicrobial in solution, through a nip roll to remove excess liquid, and into a dryer to dry the fabric to the touch, at temperatures adequate to remove excess water and other carriers without causing deterioration or conversion of the hop acid to an ineffectual form. To achieve a suitable disposable diaper in accordance with the invention, the diaper, after drying, and as packaged for consumer purchase, should have a sufficient amount of antimicrobial impregnated therein to be effective in combating *Staphylococcus aureus*. Such surface concentration may be achieved by passage of the diaper web through a bath of antimicrobial in a water or water/glycerine bath, the concentration of the antimicrobial being such as to provide the desired effective amount thereof. Passage through the bath and nip rolls at a rate appropriate to achieve an overall wet pickup of about 100 weight percent, based upon the weight of the fabric, is preferred. The impregnated fabric is then subjected to drying by passage through a dryer, typically through a stack of steam cans maintained at a suitable temperature that drying of the fabric may occur between about 200° and about 250° F. so as to dry the fabric quickly but without effecting antimicrobial activity of the compounds incorporated into the fabric. If the antimicrobial composition is applied as an alcohol solution, the drying temperature may be lowered. The dried, finished product is then led away from the dryer, rolled, cut to size, and stored, wrapped in plastic bags or the like.

The preparation of wet wipes in accordance with the invention may be similarly conducted, with the exception of the drying step. The wet wipe fabric may be any fabric conventionally used for this purpose, and the anti-microbial hop acid may preferably be incorporated in a suitable liquid, such as a glycerine or polyglycol solution, for impregnation into the wet wipe. The wipe should be passed through a bath of the liquid, and passed through a nip roll or other means to eliminate excess liquid, and then cut to the chosen size and packaged in a plastic container, bag, etc. The concentration of the antimicrobial hop acid should preferably exceed about 0.00002 to about 0.100 weight percent of the solution, so as to achieve an effective amount

thereof in the wipe at the time of usage. As in the preparation of diapers, the concentration of the antimicrobial should be sufficient to provide an effective amount thereof at the point of usage.

Although the present invention has been described in considerable detail with reference to certain preferred embodiments, one skilled in the art will appreciate that the present invention can be practiced by other than the preferred embodiments, which have been presented for purposes of illustration and not of limitation. For example, alternative methods of incorporation of the antimicrobial materials in the diapers, or in alternative materials, such as dressings or bandages, may be envisioned.

Therefore, the scope of the appended claims should not be limited to the description of the preferred embodiments contained herein.

INDUSTRIAL APPLICABILITY

The diapers and wet wipes of this invention are easily prepared using conventional apparatus and processes, employing hop acid antimicrobial materials which are derived from brewing processes by known methods.

CLAIMS

We claim:

1. A method for inhibiting the growth of *Staphylococcus aureus* on infants comprising the step of:

diapering the infant with a diaper comprising an effective amount of an antimicrobial compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof.

2. The method of claim 1, wherein said diaper is a disposable diaper.

3. The method of claim 2, wherein said compound is applied to the diaper dissolved in a liquid selected from the group consisting of water, alcohols, propylene glycol, glycerine, polyglycols, and mixtures thereof.

4. A diaper containing an antimicrobial compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof.

5. The diaper of claim 4, wherein said antimicrobial compound is present in sufficient quantity to inhibit the growth of *Staphylococcus aureus* in liquids with which it is in contact.

6. A cleansing wet wipe comprising an antimicrobial compound selected from the group consisting of tetrahydroiso-alpha acids, hexahydro-beta acids, and mixtures thereof, in a liquid selected from the group consisting of water, alcohols, propylene glycol, glycerine, polyglycols, and mixtures thereof.

7. The cleansing wet wipe of claim 6, wherein said compound is present in sufficient quantity to inhibit the growth of *Staphylococcus aureus* in liquids with which it is in contact.

ABSTRACT OF THE DISCLOSURE

Diapers and wet wipes for cleansing of infants are made anti-bacterial by the inclusion therein of hop acid derivatives, specifically tetrahydroiso-alpha acid and hexahydro-beta acid. These compounds are effective to inhibit the growth of gram-positive bacteria, and specifically chosen to combat *Staphylococcus aureus*, a primary factor in toxic shock syndrome in infants.

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0010/PTO
Rev 6/95

U.S. Department of Commerce
Patent and Trademark Office

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

[X] Declaration Submitted with Initial Filing OR [ ] Declaration Submitted after Initial Filing

Attorney Docket Number	661005.90268
First Named Inventor	Michael C. Barney
COMPLETE IF KNOWN	
Application Number	
Filing Date	Herewith
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled.

ANTIMICROBIAL DIAPERS AND WET WIPES

(Title of the Invention)

the specification of which

[X] is attached hereto

OR

[ ] was filed on (MM/DD/YYYY) _____ as United States Application Number or PCT International Application Number _____ and was amended on (MM/DD/YYYY) _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1 56

I hereby claim foreign priority benefits under Title 35, United States Code §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
N/A			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]

[ ] Additional foreign applications numbers are listed on a supplemental priority sheet attached hereto

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below

Application Number(s)	Filing Date (MM/DD/YYYY)	
N/A		[ ] Additional provisional application numbers are listed on a supplemental priority sheet attached hereto.

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DECLARATION

I hereby claim benefit under Title 35, United States Code §120 of any United States application(s), or §365(C) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application or PCT international application in the manner provided in the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number *(if applicable)*
N/A			

[ ] Additional U.S. or PCT international application numbers are listed on a supplemental priority sheet attached hereto

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and all continuation and divisional applications based thereon, and to transact all business in the Patent and Trademark Office connected therewith:

[ ] Firm Name **OR** Customer Number or label

[X] List attorney(s) and/or agent(s) name and registration number below

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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[X] Additional inventors are being named on supplemental sheet(s) attached hereto

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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

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